GE
Sensing & Inspection Technologies

# Kaye RF ValProbe®

## RF Thermal Validation System

The Kaye RF ValProbe integrates breakthrough RF Mesh technology with well-established thermal validation in situ loggers from GE Sensing.

The Kaye RF ValProbe system is intended for the validation and monitoring of environmental chambers and storage areas (i.e. stability chambers, freezers, refrigerators, warehouses, etc). The RF ValProbe system utilizes a 2.4 GHz RF Mesh network and multipleredundant data storage to provide ultra-reliable and robust communications and storage of critical validation data. Additional safeguards guarantee data integrity, storage and compliance with regulatory requirements.

The RF ValProbe system is comprised of RF wireless loggers, a base station and software. The loggers provide high accuracy measurement of temperature, humidity, and any 4 to 20mA or 0 to 10 V output.

RF ValProbe's software enables support for 2-Channel and 5-Channel RF Temperature loggers for Validation.

The software provides ease of use by incorporating features such as self-configuring of the mesh network and automatic data collection. Extensive graphing, reporting and calculation capabilities minimize data analysis and provide regulatory-compliant reports.

It is used for simplified real time validation of Stability Chambers, Freezers, Warehouses and Steam in Place Application.

imagination at work

### Features

- RF Mesh Networking technology provides reliable real time process data. Uses global 2.4 GHz RF frequencies
- Provides 100% data redundancy in both remote logger and base station in addition highly reliable RF network.
- Greater than 1 year battery life in typical use, using Standard AA Lithium batteries.
- Can operate stand-alone or with PC connected with data stored in RF Base Station
- Intuitive study set-up and extensive calculations simplify the validation and reporting process
- Best-in-class data analysis tools, including ability to graph and report in cycles and groups
- Report tool can process and create merged reports from RF ValProbe, Valprobe or Validator products
- Versions provide temperature to 0.1°C accuracy, RH to 2% RH, 4/20 mA,0 to 10 V and dry contact switch inputs, 2-Channel and 5-Channel Temperature logger
- Temperature and pressure accuracy meets requirements for ISO-17665, EN554 and EN285 sterilization requirements.
- Easy connection to Kaye Pressure transducer which is designed for harsh environment applications such as steam sterilizers and SIP systems.
- Can be directly connected to 1.5 in triclover flange via SmartGasket® or similar gasket design.

# SmartMesh™ Technology

GE's mesh networking technology is proven in many harsh environment applications. Its implementation in the Kaye product line allows up to 100 nodes to be connected in a seamless, reliable and self forming mesh network. The mesh technology permits nodes to communicate with the base station and each other, correcting for weak RF links and automatically adjusting to dynamic RF environment, e.g. a forklift truck driving into a warehouse blocking a signal. Interference from WiFi and other existing industrial RF networks is removed due to the frequency hopping features. No special knowledge or expertise is required to install or operate the Kaye RF ValProbe.

## RF Specifications & Certifications

RF 2.4GHz SmartMesh® Technology Max number wireless nodes: 100 Range: approx 300 ft/100m from one node to another Each node can act as a repeater RF Type Approval Certifications in: US, Canada, EU. Other countries in progress, please contact factory for up to date country list

## Data Redundancy

The RF SmartMesh* Technology provides a very secure, reliable transmission; however there are circumstances where RF transmission is blocked, either by placement of a logger of some intermittent physical or radiofrequency blocking of the signal. The loggers store up to 10,000 samples per sensor permitting the operation as a data logger if RF communication is not possible, e.g. one logger placed in a warehouse exhaust HVAC duct. The logger will resume transmitting data once it is in RF communication with the base station or other logger.

The base station provides data storage also, permitting the user to start a study then disconnect the PC. Data storage permits all data collected on all loggers to be stored in the base station until the PC is next connected.

Map | Motes | Data | Alarms | Network Statistics | Deta

24 Hours | Daily | Lifetime

*Daily*

| Date △1 | Data Reliability (%) | Path Stability (%) |
|---|---|---|
| 08/04/2005 | 99.998 | 85.590 |
| 08/05/2005 | 100.000 | 80.620 |
| 08/06/2005 | 99.999 | 86.260 |
| 08/07/2005 | 100.000 | 88.560 |
| 08/08/2005 | 100.000 | 92.150 |
| 08/09/2005 | 100.000 | 90.230 |
| 08/10/2005 | 99.997 | 88.300 |

*SmartMesh is a trademark of Dust Networks, Inc.

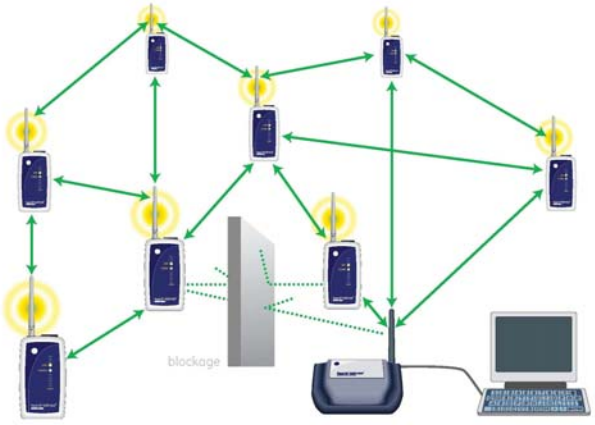
## Secure Data

There are multiple levels of transactional and data security built into the RF ValProbe system.

1. Only Kaye RF ValProbe nodes from GE Sensing are permitted to join a RF ValProbe network through the use of private keys and login registration information exchanged between the Base Station and RF ValProbe nodes at startup.
2. All data transmitted on the network is protected using secure keys, preventing non-authorized base stations or nodes eavesdropping on the data or feeding nonauthorized data into the network.
3. All data is timestamped, and identified by sending the logger's serial number. All data and meta data associated with a qualification study is stored in a single secure, tamperproof file.
4. DoS (Denial of Service) attacks are prevented by Message Integrity Codes.

## Automatic Network Formation and Optimization

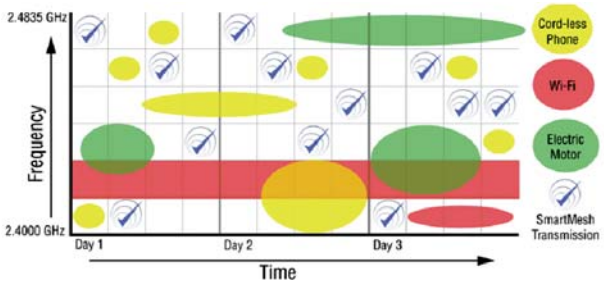
SmartMesh networks are self forming and self-optimizing Every node can discover neighbors, measure RF signal strength, acquire synchronization and frequency hopping information, and establish best paths and links with neighbors. This ability to dynamically reconfigure is dictated by RF connectivity and/or network performance requirements.



## Interference

The SmartMesh technology combines frequency hopping with TDMA (Time Division Multiple Access). In addition the mesh protocol permits the system to learn about the RF environment and dynamically adjust the network parameters to best fit the current situation.

The network provides an accurate time reference for the whole network, ensuring all loggers and the base station are time synchronized correctly. Each data sample is timestamped with this network time.




## Coexistence with Other RF Systems

The RF ValProbe complies with the IEEE 802.15.4, the preeminent RF sensor network standard. Features like frequency hopping, listen-before-you-talk and channel blacklisting prevents other RF networks being affected by the RF ValProbe.

# Software Features

## Historical graphing

Once a study has been started, user can connect his PC anytime to the base station and retrieve all the data from the base station on the real time graph to view the data that has been logged by the loggers to that point. This will enable viewing historical data without having to stop the study at the base station.

## RF Map

Users can graphically view the RF Signal strength of the loggers and their connections to other loggers and basestation for stronger RF networks. A background image can also be set for the RF map to position the loggers on a real floor plan. The users can use this as back up documentation for looking at the position of the loggers at a later time.

## Real time graphing calculations

Real time graphing provides min/max/avg calculations for the RH and Temp parameters of all the loggers being plotted in the real time graph.

## Alarming

User can set low and high alarms on the real time graph to see if any loggers have crossed the limits. The limits can also be labeled by the user.

## Auto Calibration/Verification

RF Valprobe System enables auto calibration/verification for the users when using the RF loggers, GE Kaye IRTD, GE Kaye Temperature baths. This enables the user to select the set points and let the software run the calibration/ verification including loading of offsets into the loggers automatically.

The software will control the Kaye drywells and read the reference temperature data from a connected Kaye IRTD permitting full automatic calibration with the Kaye calibration products. Providing that the users configure the communications port , access to automatic calibration will be permitted. Calibration is still permitted if either drywells or IRTD is not present, in which case either semi-automatic or manual mode calibration is used.

## Independent Report Wizard

Along with the RF ValProbe software, there is an additional software program called the “Kaye Report Wizard”. This report wizard permits the user to launch the “Create Reports” section independently of the Kaye product installed on the user’s PC. The “Create Reports” button of the standard software will continue to operate as in previous versions. The user can decide install the Report Wizard in a separate folder and use it to report on all 3 Kaye products: Validator, Valprobe or RF Valprobe.

# Reports

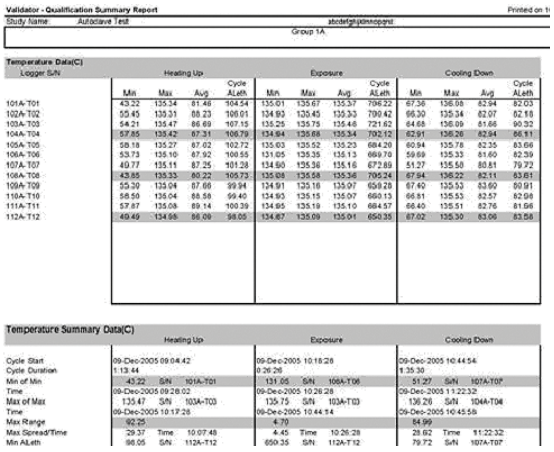
The Kaye RF ValProbe Software includes an intuitive, yet powerful reporting utility for generating Set-Up, Calibration, Qualification, Graph and Calibration Verification reports to document validation study results. Reports are generated from secure data files that can only be read by the system software. Upon study completion, process cycles to be analyzed are defined using the intuitive system graphic feature.

## Qualification

Reports present raw process data for individual sensors, statistical calculations selected during study setup, and accumulated lethality for individual sensors.

Summary reports present study set-up details and poststudy user comments, along with group interval and lethality calculations, as well as data for each group and cycle. Use of the Summary and Group Summary Reports can greatly reduce the need to export data for manipulation in Excel®.

Any action affecting user data can be permanently captured in a comprehensive audit trail, which can be automatically stored at a network location. System administrators can now have fully automated management of passwords, audit trails and data files across all validation groups.

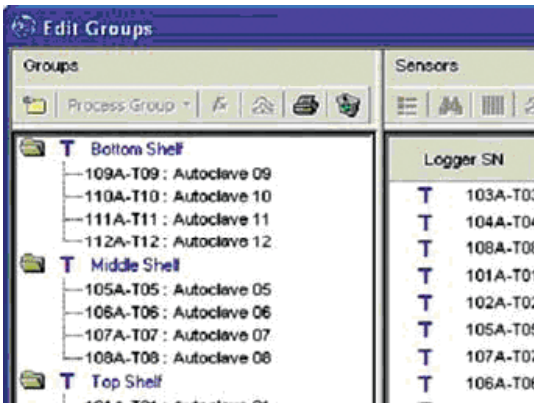

Validator - Qualification Summary Report

Temperature Data(C)

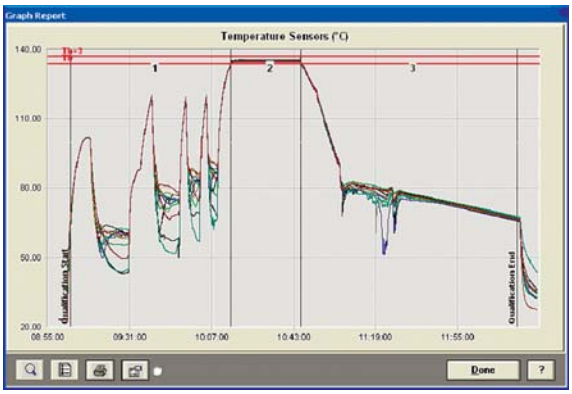
Temperature Summary Data(C)

Summary Report

Data files can be merged from multiple RF ValProbe and ValProbe studies. Users can add unlimited cycles, separating qualification data into specific process phases, and create up to 25 groups with their own calculations and graphs during reporting,




A powerful graphing utility within the system software greatly simplifies process analysis and reporting. Sliding vertical axes enable the operator to flag and define process transition points, eliminating unnecessary reporting and streamlining the review process. The graph utility features increased flexibility for graph customization, including specifying X and Y axis ranges, background colors, line styles and labeled limit lines.

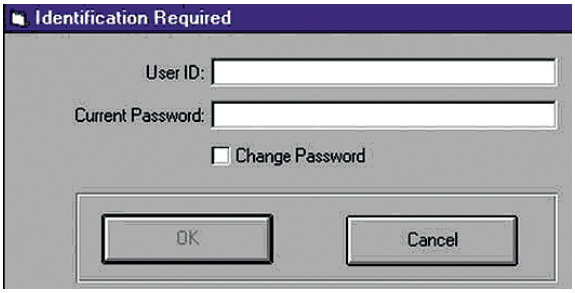



Graph report

## Security, Passwords and Audit Trails

The Kaye RF ValProbe is specifically designed to enable compliance with FDA 21 CFR Part 11. All recorded data, including calibration offsets, set-up parameters, and administrative tasks are saved in secure, encrypted, tamper-proof electronic records in a format accessible only through the system software.

All user inputs which could impact user data, for example starting a study or running a calibration, are protected via secure username/password logins, and are all logged in the secure audit trail database.




Login Request

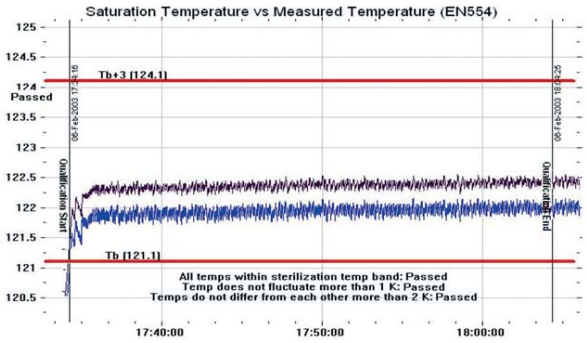
The reporting software has been enhanced to enable easy review and printing of the audit trail based on dates, times and/or events for example, the system administrator can select to review “all failed login attempts for the last 30 days.” There is now also notification to the user and logged entries in the audit trail if files are tampered with or deleted from within Windows Explorer™

## Mean Kinetic Temperature

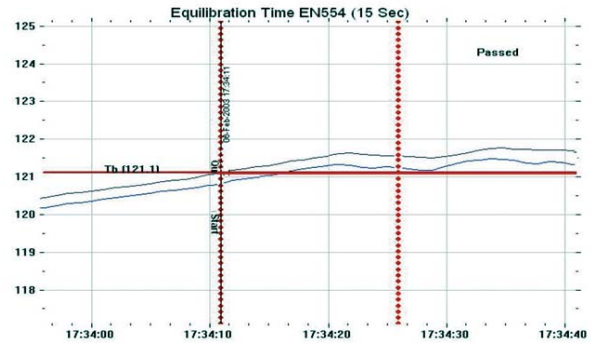
The Reporting Software provides Mean Kinetic Temperature calculation to the user. Mean Kinetic Temperature (MKT) is single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures.

## Saturated Steam Calculation

Easy integration between temperature and pressure enables EN554 compliance and determination of Saturated Steam conditions


Saturation Temperature vs Measured Temperature (EN554)
Tb+3 (124.1)
Passed
Tb (121.1)
All temps within sterilization temp band: Passed
Temp does not fluctuate more than 1 K: Passed
Temps do not differ from each other more than 2 K: Passed
17:40:00
17:50:00
18:00:00

### Equilibration Calculation




# Steam in Place Application

The Kaye RF ValProbe® system permits up to 100 distributed nodes, measuring both temperature and pressure. The system allows large SIP systems to be validated or re-validated in single large sections without the need for repeated SIP studies.

The temperature sensor is a precision small diameter bendable type RTD designed to permit easy access to pipes and vessels through gaskets. The temperature probe remains in place and can be fed along pipe work or placed into stainless vessels or filter bodies.

The high accuracy pressure transducer is designed for 121C and 134C operation and is calibration compliant to ISO 17025 at these extended temperatures. It is powered externally, easy to connect and simple to configurate with the RF ValProbe® software.

# Specifications

### Environmental
Body: -40°C to 60°C, 0 to 95%RH non condensing
- External probe: -196°C to 200°C
- Logger Dimensions: 190 mm x 127 mm x 45 mm (7.5 in x 5 in x 1.75)
- Base Station Dimensions: 64 mm x 32 mm x 15 mm (2.5 in x 1.25 in x 5 in)

## Temperature

### Single Channel External Sensor
- ±0.1°C, range 0°C to +60°C
- ±0.2°C, range -22°C to 0°C
- ±0.5°C, range -80°C to –22°C
- ±2.0°C, @ -196°C

### For 2 and 5 Channel Temperature Loggers:
±0.1C range –80°C to 130°C

### RH
- 2% from 10 to 90%RH
- 5% from 0 to 10%, 90 to 100%RH
- 3% at 40°C, 75%RH
- Certificate states ICH Points

### Auxiliary Inputs
- Contact: dry
- Voltage and current 0.5% FS

### Battery Life (Varies ±10%)
1 min sample rate: 8000 hours

## System Documentation

### IQ/OQ Protocol
The Installation Qualification/Operational Qualification Protocol defines a set of procedures to ensure that the Kaye Validator system is properly installed and operated correctly, and is adequately documented and controlled according to cGMP requirements. The documents are provided in hard copy and on CD, allowing users to modify the documentation to suit specific organizational requirements.

Updates and addenda are available through the Kaye website.

## Services

GE Sensing provides a complete range of services for the RF ValProbe® product range:
- Onsite installation,commissioning and IQ/OQ for RF ValProbe® system.
- Operator training and technical support.
- Maintenance agreements.
- Factory calibration.
- Rental services.

## Validation Reference

The Kaye Validator system is supported with Design Qualification documentation. The Validation Reference Binder provides a comprehensive overview of the GE Quality Policy, description of ISO 9001 implementation and support procedures, and standards for the development, testing, and maintenance of hardware and software. Quality Control documents, Development procedures, Quality Assurance procedures, Release documents, and Quality Assurance test documentation are all included.

# Ordering Information

## RF Thermal Validation System

| | |
|---|---|
| dsX2558 | RF ValProbe Base Station includes USB Cable, PC Software and User Manual |
| X2570-12 | Logger with Single 12" External Temperature Probe, Internal RH Sensor, no auxiliary inputs |
| X2570-18 | Logger with Single 18" External Temperature Probe, Internal RH Sensor, no auxiliary inputs |
| X2570-36 | Logger with Single 36" External Temperature Probe, Internal RH Sensor, no auxiliary inputs |
| X2570S-L | Specify 1 or 3 standard lenght; custom length available on request |
| X2571-12 | Logger with Single 12" External Temperature Probe, Internal RH Sensor with contact switch and 4-20mA current loop auxiliary Input |
| X2571-18 | Logger with Single 18" External Temperature Probe, Internal RH Sensor with contact switch and 4-20mA current loop auxiliary Input |
| X2571-36 | Logger with Single 36" External Temperature Probe, Internal RH Sensor with contact switch and 4-20mA current loop auxiliary Input |
| X2571S-L | Specify 1 or 3 standard lenght; custom length available on request |
| X2572-12 | Logger with Single 12" External Temperature Probe, Internal RH Sensor with contact switch and 0-10V Voltage auxiliary Input |
| X2572-18 | Logger with Single 18" External Temperature Probe, Internal RH Sensor with contact switch and 0-10V Voltage auxiliary Input |
| X2572-36 | Logger with Single 36" External Temperature Probe, Internal RH Sensor with contact switch and 0-10V Voltage auxiliary Input" |
| X2572S-L | Specify 1 or 3 standard lenght; custom length available on request |
| X2563 | Internal Temperature and RH Logger, Voltage and Contact Auxiliary |
| X2564 | Internal Temperature and RH Logger, 4/20mA Current and Contact Auxiliary |
| X6030 | RF ValProbe IQ/OQ Protocol |
| X6035 | RF ValProbe Validation Reference (DQ) Package |
| X2573-3 | RF ValProbe Dual Channel Logger with external 3" Temperature Probes |
| X2573-6 | RF ValProbe Dual Channel Logger with external 6" Temperature Probes |
| X2573S-L | RF ValProbe Dual Channel Logger with external L' Temperature Probes |
| X2574-6 | RF ValProbe Five Channel Logger with external 6" Temperature Probes |
| X2574-15 | RF ValProbe Five Channel Logger with external 15" Temperature Probes |
| X2574S-L | RF ValProbe Five Channel Logge with external L' Temperature Probes |

## RF Steam in Place Application

| | |
|---|---|
| X2570-20B | RF ValProbe® Logger with External 20" Bendable Temperature Probe and RH Sensor |
| X2571-20B | RF ValProbe® with External 20" Bendable temperature Probe, RH Sensor, 0-10v Voltage input and Contact Closure which accomodates Kaye Pressure Transducer |
| X2572-20B | RF ValProbe® with External 20" Bendable temperature Probe, RH Sensor, 4-20mA Current Input and contact closure |
| X2576 | Kaye Pressure Transducer 110V |
| X2576E | Kaye Pressure Transducer 220V |
| K0448 | Feedthru triclover clamp |
| M1989 | SmartGasket® Silicone gasket |

* Please contact factory if different probe lengths are required.

www.gesensing.com/kayeproducts

920-421D

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